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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,353	05/02/1997	YESOOK KIM	PC9563JTJ	4835

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GREGG C BENSON  
PFIZER INC  
PATENT DEPARTMENT  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

08/850,353

### Applicant(s)

KIM, YESOOK

### Examiner

EVERETT WHITE

### Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Disposition of Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priorities under 35 U.S.C. §§ 119 and 120

- 2) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 3) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 4) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The amendment filed May 24, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) Claims 4-15 previously canceled;
  - (B) Comments regarding Office Action have been provided drawn to:
    - (a) 102(e) rejection, which has been withdrawn;
    - (b) 102(a) rejection, which has been maintained for the reasons of record.
2. Claims 1-3 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

1. Claims 1-3 stand rejected under 35 U.S.C. 102(a) as being anticipated by Chiesi et al (US Patent No. 5,773,029) for the reasons disclosed on pages 3-5 of the Office Action mailed November 20, 2003.

Applicant's arguments filed May 24, 2004 have been fully considered but they are not persuasive. Applicant argues against the rejection on the ground that the Chiesi et al patent does not teach locating a salt having a solubility greater than or equal to a target solubility as required by Applicants' Claim 1 and does not teach comparison and selection steps as required by Claims 2 and 3. This argument is not persuasive since the instant Claims do not set forth the target solubility of a specific salt or the solubility of specific salts that can be used for comparison. The instant claims do not set forth the equilibrium solubility of specific salts in an aqueous cyclodextrin solution, nor does the instant claims set forth specific steps of how the solubility of the salts are measured. However, contrary to the instant Claims, the Chiesi et al patent does recite the solubility of different compounds and salts thereof under various conditions, at equilibrium, that can be compared in order to select a desired compound or salt. The Chiesi et al patent discloses multicomponent inclusion complexes wherein a multicomponent inclusion complex comprises an acidic drug, a base and a cyclodextrin, wherein a complex is obtained by simultaneous salt formation and complexation. See column 2, lines 54-61

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for examples of cyclodextrin derivatives that can be used in the preparation of the inclusion complexes which include alfa and gamma CD, hydroxypropyl- $\beta$ CD (HPBCD), dimethyl- $\beta$ CD (DIMEB), random methylated - $\beta$ -cyclodextrin (RAMED) and other cyclodextrin derivatives. In the next 2 paragraphs in this column Chiesi et al discloses that the basic component of the complexes according to the invention can be of both inorganic and organic nature, which specific examples include alkali or alkaline earth hydroxides, secondary or tertiary amines, such diethanolamine, triethanolamine, diethylamine, methylamine, trimethamine (TRS) and the like. In the first two paragraphs in column 3 Chiesi et al describes the type of acidic drugs used in the patent which is set forth to mean any drug having at least an acidic function such as a carboxy, sulfonic, sulfonylamino, sulfonylureic, phenol group and the like. Examples of classes of the acidic drugs disclosed by Chiesi et al comprises oxicams, hypoglycemic sulfonylureas, benzothiadiazine diuretics, barbituric acids, arylacetic and arylpropionic antiinflammatory acids. See column 6, lines 57 to 62 wherein Chiesi et al describes the information disclosed in Tables 1 and 4, which set forth the equilibrium solubility of some drugs used for the preparation of the complexes of the invention therein, wherein respective sodium salts and the physical mixture with  $\beta$ CD is used to determine the maximum solubility conditions at equilibrium. Also see Tables 2 and 4 wherein the instant solubility is determined for multicomponents Glibenclamide/ $\beta$ CD/NaOH, Glibenclamide/ $\beta$ CD/Diethanolamine, Piroxican/RAMEB/NaOH, and Piroxican/HP $\beta$ CD /NaOH. The information set forth in Tables 1, 2 and 4 of the Chiesi et al patent allows for a comparison of the solubility properties of a series of salt, including salts of medicinal compounds as set forth in Claim 2 and salts for use to make a composition of matter comprising an inclusion complex of a salt in a cyclodextrin as set forth in Claim 3. The method described in the instant claims does not set forth unexpected results. Accordingly, the method described in the Chiesi et al patent for preparing salts of multicomponent inclusion complexes anticipate the method of locating one or more salts of a compound and a method of determining a useful salt from within a series of salts as instantly claimed.

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**Summary**

2. All the pending claims are rejected.

**Conclusion**

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Examiner's Telephone Number, Fax Number, and Other Information**


For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
E. White

  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600